K101601

510(K) Summary

SEP 23 2010

Submitter:	Cynosure, Inc. 5 Carlisle Road Westford, MA 01886
Contact:	Anthony Burns Director of Regulatory Affairs
Date Summary Prepared:	June 2, 2010
Device Trade Name:	Affirm DO Diode Laser
Common Name:	Medical Laser System
Classification Name:	Instrument, Surgical, Powered, Laser 79-GEX 21 CFR 878.4810
Equivalent Device:	Cynosure YAG MIR Family Laser
Device Description:	Affirm DO is a diode laser. It is a laser with a wavelength of 1440 nm. Laser activation is by footswitch. Overall weight of the laser is 15 Kg, and the size is 25 x 9 x 18 cm (HxWxD). Electrical requirement is 115 VAC, 15A, 50-60 Hz, single phase.
Intended Use:	The Affirm DO is indicated for use in general surgery and dermatology for the coagulation of soft tissue. It is also indicated for the treatment of periorbital and perioral wrinkles, and pigmented lesions.
Comparison:	TheAffirm DO Diode laser has the same indication for uses, the same principle of operation, the same wavelength and similar pulse energy range as the predicate devices.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The Affirm DO Diode laser is a safe and effective device for the intended uses.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cynosure, Inc.
% Mr. Anthony Burns
Director of Regulatory Affairs
5 Carlisle Road
Westford, Massachusetts 01886

SEP 2 3 2010

Re: K101601
Trade/Device Name: Affirm DO Diode Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 09, 2010
Received: September 20, 2010

Dear Mr. Burns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

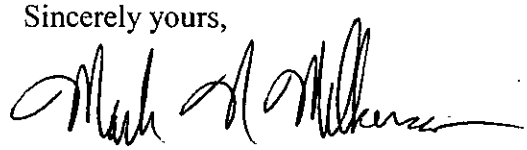
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

SEP 2 3 2010

510(k) Number (if known): K101601

Device Name: Affirm DO Diode Laser

Indications For Use:
The Affirm DO Diode laser device is indicated for use in general surgery and dermatology for the coagulation of soft tissue. It is also indicated for the treatment of periorbital and perioral wrinkles, and pigmented lesions.

Prescription Use √ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use_____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mam

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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